340B REFORM:

FEDERAL RECOMMENDATIONS & STATE-BASED ALTERNATIVES

The 340B Drug Pricing Program (340B Program) is a federal program intended to support covered entities (CEs) serving low-income and uninsured patients with limited resources by providing access to discounted prescription drugs.[1] Covered entities are specific types of safety-net providers defined in federal statute, such as certain hospitals, federally qualified health centers (FQHCs), Ryan White HIV/AIDS clinics, and other providers that care for a high share of low-income or uninsured individuals.[2] In recent years, the Program has drawn increased scrutiny as some hospitals have expanded 340B participation beyond eligible patients and intended communities. Stakeholders have raised concerns that 340B has, in some cases, become a driver of hospital profitability without a corresponding increase in charity care or direct patient benefits.[3] Additionally, some intermediaries have developed business models focused on directing prescriptions through 340B Program contract pharmacies to capture program discounts.

As a federally created and regulated program, federal reform for the 340B program is the most direct path to address its challenges. Aimed Alliance supports federal policy solutions to strengthen program integrity and better align benefits with the patients and communities the program was designed to serve. At the same time, states are exploring policy approaches to promote transparency and accountability within 340B while awaiting federal reforms. Aimed Alliance supports state-based efforts that provide transparency into the 340B program. The chart below outlines recommended federal reforms alongside state-based alternatives.

FEDERAL POLICY RECOMMENDATIONS

Give HRSA Clear Regulatory Authority

The Health Resources and Services Administration (HRSA) struggles to oversee the 340B Program because its enforcement authority is currently limited to issuing non-binding guidance.[4] Congress should grant HRSA explicit rulemaking authority to establish formal, enforceable regulations governing contract pharmacy arrangements and compliance standards. Providing this authority would enable HRSA to more effectively oversee the program and safeguard its integrity.

Strengthen Audit Integrity

Current HRSA audits rely heavily on self-attestation, lack standardized methods for assessing the scope of noncompliance, and may be closed without verification of corrective actions.[5] This audit process leads to inconsistent and incomplete oversight, allowing covered entities with identified violations to continue noncompliant practices without implementing adequate corrections. Reform should require a clearly defined framework, including a specified look-back period to assess the full scope of noncompliance and a requirement that CEs demonstrate successful implementation of corrective action plans before audits are closed.[6]

Strengthen Eligibility Verification for Covered Entities

HRSA's current oversight of nongovernmental hospital[i] eligibility relies heavily on self-reported data. This approach has resulted in inconsistent verification of nonprofit status, government contracts, or compliance with community benefit obligations, allowing potentially ineligible hospitals to participate in the 340B Program.[ii,7] To restore program integrity, reform should establish a reliable, ongoing validation process requiring all participating nongovernmental hospitals, not just new applicants, to submit official documentation demonstrating continued eligibility.[8]

Expand HRSA Staffing and Resources to Ensure Program Sustainability

HRSA currently audits only 200 CEs annually, representing less than 2 percent of total participants.[9] Of those audited, 72 percent have been found to have at least one instance of noncompliance.[10] This limited audit capacity contributes to program vulnerabilities, including duplicate discounts and participation by ineligible entities. To address these gaps, HRSA should receive additional resources to increase audit frequency and capacity, as well as to conduct follow-up re-audits. These assessments should include reviews of submitted documentation, verification of government contracts, and periodic recertification of eligibility.

Increase Transparency of Contract Pharmacy Arrangements

CEs are responsible for overseeing their contract pharmacies to ensure all 340B distributions comply with program requirements.[11] However, HRSA's limited visibility into these arrangements, combined with the absence of clear standards, has allowed for rapid expansion of contract pharmacies.[12] To improve accountability, HRSA should require site-specific registration of all contract pharmacy relationships and establish minimum oversight standards and annual frequency of compliance reviews.[13]

Establish a Formal "Patient" Definition

Although the 340B statute prohibits drug diversion, it lacks a statutory definition of "patient," leading entities to rely on HRSA's outdated, non-binding 1996 guidance to justify broad interpretations.[14] To resolve this ambiguity, federal policy should mandate a clear definition that requires a direct clinical connection between the CE and the patient.[15] This ensures that every 340B prescription originates from a genuine, substantive healthcare encounter where the provider maintains ongoing, direct responsibility for the patient's care within a timely clinical window.[16]

i. Private, nonprofit hospitals that have contracts with state or local governments to provide health care services to low-income individuals who are not eligible for Medicare or Medicaid. GAO, 340B Drug Discount Program: Agency Oversight Has Improved, but Actions Needed to Address Weaknesses, 1, 8 (2025).

ii. While HRSA began requiring new registrants to submit government contracts in 2020, existing participants remain largely exempt from this documentation standard, relying instead on Medicare cost report data that fails to confirm nonprofit status, such as IRS filings. Id. at 10.

STATE-BASED ALTERNATIVES

Increase Reporting Requirements

State reform efforts should require comprehensive reporting on key financial metrics, such as drug acquisition costs, insurance revenues, and aggregated payments made to contract pharmacies.[17] Greater transparency is necessary to understand how program revenues are generated and whether benefits are reaching patients. This data can also help inform federal reforms.

> **Example:** Minnesota requires CEs to annually report data related to their 340B prescription drug purchases and payments to the Department of Health.[18] These disclosures revealed that CEs generated at least $1.34 billion in net 340B revenue in 2024, more than double the $630 million reported in 2023.[19]

Establish Patient Affordability Requirements

While the 340B Program is intended to serve low-income populations, there is no requirement that savings be passed through in ways that directly benefit patients, such as lower out-of-pocket costs, or that program-generated revenue be reinvested into safety-net care.

Evidence suggests that many 340B hospitals do not consistently direct these revenues toward such purposes.[20] To address this gap, patient affordability requirements should be established to ensure that qualifying low-income and uninsured patients directly benefit from the program, including through reduced out-of-pocket costs for prescription medications and other clearly defined patient-centered uses of 340B savings.

Medicaid Pharmacy Carve-Out Model

States can "carve-out" prescription drug benefits from Medicaid managed care. Under this approach, states remove pharmacy benefit administration from managed care organizations (MCOs) and return it to direct state control under a fee-for-service model. By doing so, states gain full visibility into prescription drug costs, centralize and leverage negotiation power, utilize a single drug formulary with standardized utilization management protocols, and address the growth of the 340B program and associated reductions in state rebate revenue.[21]

> **Example:** New York carved prescription drug benefits out of Medicaid managed care and returned pharmacy administration to the state.[22] The state projected that this transition would generate $400 million in savings in its first year and $2 billion over two years.[23] This example illustrates how state Medicaid design can influence overall program expenditures and the ability to capture pharmacy-related cost savings.

Fix Duplicate Discount Prevention

HRSA's oversight of duplicate discounts is limited to Medicaid fee-for-service, and does not extend to Medicaid managed care, where most 340B utilization occurs.[24] In addition, HRSA does not require repayment for violations or assess whether state Medicaid policies contribute to duplicate discounts.[25] To address these gaps, states should require use of claim-level identifiers, modifiers, or other standardized mechanisms to distinguish 340B drugs in Medicaid managed care claims, extend duplicate discount prevention requirements to managed care, and establish state-administered processes to identify and require repayment to manufacturers when they occur.[26]

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